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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/711,886	10/12/2004	Yandong Jiang	022727-0117	5885
21125	7590	11/14/2007	EXAMINER	
NUTTER MCCLENNEN & FISH LLP			JACKSON, BRANDON LEE	
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155 SEAPORT BOULEVARD			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No.	Applicant(s)
	10/711,886	JIANG, YANDONG
	Examiner Brandon Jackson	Art Unit 3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 September 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3-17,19-22 and 24-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,3-17,19-22 and 24-32 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/7/2007.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

This action is in response to amendments/arguments filed 9/20/2007. Currently, claims 1, 3-17, 19-22, and 24-32 are pending in the instant application.

Response to Arguments

Applicant's arguments with respect to claims 1, 3-17, 19-22, and 24-32 have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of

copending Application No. 11021157 (US 2005/0166929) in view of Tuck (US 6,923,181).

The limitations of claim 1 of the instant invention can be found in claim 1 of Application No. '157 except for the limitation of a nasal mask as part of the device. However, Tuck teaches a nasal mask (Figure 2) adapted to deliver gases through the patient's nasal passageway [0034]. Since this is a nasal mask, the delivery of gas taught by Tuck is through the nasal passageway. Therefore, it would have been obvious, to one having ordinary skill in the art at the time of the invention, to modify claim 1 of the instant application so that it would include the nasal mask taught by Tuck, as making this modification would result in a patient being able to obtain an artificial gas supply.

The limitations of claim 3 of the instant invention can be found in claim 1 of Application No. '157 except for the limitation that the mouthpiece "is effective to prevent the patient's soft tissues of the upper airway from collapsing." However the mouthpiece is capable to be adapted to perform this function.

The limitations of claim 4 of the instant invention can be found in claim 2 of Application No. '157.

The limitations of claim 5 of the instant invention can be found in claim 1 of Application No. '157. The difference between claim 5 of the instant invention and claim 1 of the application lies in the fact that the instant application claim positively recites connection of the tube to a negative pressure generator while application '157, claim 1, recites that that tube is "adapted to be connected to negative pressure generator."

However, it is obvious that the device claimed in each application is capable of being connected to a negative pressure generator, and so they are not patentably distinct from one another.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-17, 19-22, and 24-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hart (US Patent 5,957,133) in view of Thornton (US Patent 6,571,798) and Fitton (US Patent 6,536,424). Hart discloses an open airway system (10) comprising a mouthpiece (fig. 1) adapted to seal (fig. 2) an oral cavity (14), a negative pressure generator (20) coupled to the mouthpiece (fig. 1) via hollow elongate tube (22) to prevent the user's (16) soft tissue of the upper airway from collapsing (col. 3, lines 65). The oral cavity (14) is sealed when the oral cavity is closed with a negative

pressure generator (20) running because the suction will hold the oral cavity closed after it has been closed. The mouthpiece (fig. 1) does not impinge (fig. 2) on the tongue (36) of the user (16). The mouthpiece (fig. 1) has upper and lower indentations (32, 34) that conform to the anatomy of the user's upper and lower teeth (40, 42). The negative pressure generator operates in a range of about 0 cm to 60 cm of water (col. 4, lines 27-30). Hart fails to disclose the mouthpiece having protrusion that is adapted to both expand the oral cavity and prevent air from entering the patient's mouth, a nasal mask adapted to deliver gas through the patient's nasal airway coupled with the mouthpiece and a device selected from CPAP device, mechanical ventilation device, and a PEP device, wherein the first tubular member delivers gases and the second tubular member is adapted to allow gas to be taken from the nasal passage, wherein the tubular member seal the nasal passage and are coupled with the mouthpiece. Hart also fails to disclose a negative pressure generator is coupled to a hollow elongate member extending from the mouthpiece. Thornton discloses an open airway system (8) comprising a mouthpiece (10), a venting seal (24), a CPAP interface/nasal mask (44) including two nasal pillows/tubular members (30) to seal the nasal airway and provide gas to the nasal airway. One pillow (30) provides gas to the nasal airway and the other pillow (30) allows gas to be taken from the nasal airway. The CPAP interface (44) is coupled (fig. 1) to the mouthpiece (10). Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to replace the mouthpiece (10), as taught by Thornton, with the mouthpiece (fig. 1) tube (22) and negative air pressure generator (20) of Hart. Thornton teaches (col. 6, lines 33-44) that the device of can be

any suitable oral appliance and may be constructed to satisfy the user's particular needs. Fitton teaches a mouthpiece (100) comprising a protrusion (110) that expands that seals and expands the oral cavity. The protrusion (110) extends between the upper and lower portions of the mouthpiece (110) and can be adapted to be positioned between the patient's lips (fig. 6). The mouthpiece (110) is also adapted to be used with a peripheral system (i.e. negative pressure generator) (col. 2, lines 17-19). Therefore it would be obvious to one of ordinary skill in the art at the time of the invention to substitute the venting seal (24) for the protrusion (110), as taught by Fitton, because the Thornton reference states the venting seal can be customized to fit the particular user's facial features or any other of the user's particular needs (col. 6, lines 58-60).

With respect to claims 17, 19-22, 24-27, and 29, Hart/Thornton teaches all the structural elements of the claimed invention; therefore the method steps would be obvious because they would have resulted from the use of the Hart/Thornton device. The Hart/Thornton device is fully capable of allowing normal swallowing and breathing or else it might kill the user. Also the negative pressure created within a substantially sealed oral cavity is further effective to remove secretions therefrom, as secretions would be drawn towards the flow of negative pressure leaving the oral cavity.

With respect to claim 28, the use of the negative pressure generator to remove air from the substantially sealed cavity at a rate that is in the range of about 0cc/minute to 50cc/minute has been taken to be an intended use recitation of the negative pressure generator apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the

claimed apparatus from a prior art apparatus satisfying the claimed structural limitation. *Ex parte Masham*, 2 USPQ2d 1647 (1987). *In re Paulsen*, 30 F. 3d 1475, 31 USPQ 2d 1671(Fed Cir. 1994).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon Jackson whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon Jackson 11/7/07
Brandon Jackson
Examiner
Art Unit 3772

BLJ

Patricia Bianco
PATRICIA BIANCO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700
11/8/07